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Appl. No. 09/665,852 Response Dated: February 17, 2005 Reply to Office Action of December 17, 2004



## REMARKS/ARGUMENTS

Claims 1-9, 11-12, 14-15, 17-20, and 28-30 are presently pending. Claims 1-9, 11-12, 14-15 and 17-20 are allowed.

Claim 28 has been amended. Support for this amendment may be found in claims 14 and 15, and in the specification at page 28, lines 4-18. No new matter was added by way of this amendment.

## Claim Rejections

The Examiner rejects claims 28-30 under 35 U.S.C. §112, second paragraph, for an alleged lack of clarity in the language of claim 28. The Examiner asserts that it is unclear if the phrase "in the presence of host cells" modifies the rAAV preparation or the intervening phrase, "absent contaminating helper virus or wild-type virus".

In order to provide greater clarity in the claims and in an effort to place the claims in condition for allowance, Applicants have amended claim 28 to set apart the intervening phrase "absent contaminating helper virus or wild-type virus" by commas, and have moved the phrase to follow "the presence of host cells" language, making clear that the intervening phrase is intended to modify the preparation - rAAV in the presence of host cells.

In view of the amendments to claim 28 and these remarks, Applicants request withdrawal of the rejection of this claim, and of dependent claims 29 and 30.

The Examiner rejects claims 28-30 under 35 U.S.C. §102(e), as being allegedly anticipated by U.S. Patent Publication No. 2004/0018627 A1 ("Natsoulis", priority claimed to August 3, 1995). This rejection stems from the alleged lack of clarity, which was addressed in the response to the 35 U.S.C. §112 rejection.

The Examinet indicates in the Action at page 3, last paragraph, that the rejection is based upon the assumption that the host cells in claim 28 refer to the cells used

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to produce the rAAV, as opposed to a reading of the claim that the rAAV are in the presence of the host cells. In accordance with this reading of the claims as product-by-process claims, the claims are rejected over the product of Natsoulis.

Applicants respectfully disagree with the Examiner's reading of claims 28-30. In order to provide greater clarity in the claims and in an effort to place the claims in condition for allowance, Applicants have amended claim 28 to set apart the intervening phrase "absent contaminating helper virus or wild-type virus" by commas and moved the phrase to follow "the presence of host cells" language, making clear that the intervening phrase is intended to modify the preparation - rAAV in the presence of host cells.

Claim 28, as amended, is a product-by-process claim directed to a preparation of rAAV and host cells. The preparation does not contain contaminating helper virus or wild-type virus. Further, the rAAV in the preparation is produced by culturing the host cells of the preparation. In other words, the amendments to claim 28 clarify that the host cells referred to are both used to prepare the rAAV of the preparation, and present in the preparation.

Accordingly, the Examiner's rejection and remarks regarding <u>Natsoulis</u> are moot, as the Examiner indicates that this rejection would not have been raised based upon a reading of claim 28 that "the rAAV are in the presence of the cells". (Office Action at page 3, last paragraph, fourth line) <u>Natsoulis</u> does not describe a preparation comprising rAAV in the presence of host cells.

In view of the amendments to claim 28 and these remarks, Applicants request withdrawal of the rejection of this claim, and of dependent claims 29 and 30.

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In view of the amendments and remarks above, Applicants respectfully request that the Examiner withdraw all outstanding rejections and allow the application to pass to issue. The Director is hereby authorized to charge any deficiency or credit any overpayment in any fee due with this paper to our deposit account number 08-3040.

Respectfully submitted,

HOWSON AND HOWSON Attorneys for Applicants

Cathy A. Lodroff

Registration No. 33,980

Spring House Corporate Center

Box 457

Spring House, PA 19477

(215) 540-9200